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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,956	02/12/2002	Mary Lynne Hedley	08191-022001	6983

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,956	HEDLEY, MARY LYNNE	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1- 32* is/are pending in the application.

4a) Of the above claim(s) *13, 17, and 19- 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1- 6, 8- 12, 14- 16, and 18* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6 MAY 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 2 April 2004 is acknowledged. The traversal is on the ground(s) that claim 1 is broadly directed and it is improper to make applicant elect a preventative or therapeutic method because it would force them to rewrite the claim and limit the invention. This is found persuasive in part. The required choice between "preventing" and "therapeutic" in the restriction requirement is withdrawn. Claim 1 is a linking claim as detailed in the restriction requirement. The linking claims will be examined to the extent of the elected invention and if found allowable as written, then the linked inventions will be examined. Claim 17 was inadvertently included in the list of generic claims and will be withdrawn because it reads on the non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13, 17, and 19- 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claims 1- 12, 14- 16, and18.

Information Disclosure Statement

A copy of the signed and initialed IDS is enclosed.

Claim Objections

Claim 8 is objected to because of the following informalities: It depends from itself and is a substantial duplicate of claim 7. Appropriate correction is required.

Applicant is advised that should claim 7 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 12, 14- 16, and18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear in what direction the immune response is modulated. Is it up or down? Is the immune response the problem and it is desired to reduce it or is the immune response not enough and needs to be increased? In claims 14 and 15, it is not clear how the nucleic acid is expressed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Krieg (WO document, from IDS).

The claims are drawn to a method of modulating the immune response in a mammal that is at risk of a bladder disorder by administering an unmethylated CpG sequence.

The method is interpreted to treat any mammal because any mammal with a bladder would be potentially at risk for a bladder disorder.

Krieg teaches a method of administering an unmethylated CpG nucleotide to a mammal to treat inflammatory diseases mediated by immune responses and that this treatment is applicable to a broad range of conditions (page 42, lines 6- 16) and that the CpG can be administered by any mode that delivers the nucleotide to the desired surface (page 45, lines 19- 24) and the response modulates the Th1 response (page 65, lines 18 and 19).

While Krieg does not teach bladder disorders, the CpG is administered to mammals with bladders and thus meets the limitation of the claims.

Thus, Krieg anticipates the invention.

Claims 1- 3, 9- 12, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters *et al.* (1997, from IDS).

The claims are drawn to a method of modulating the immune response in a mammal that has or is at risk of a bladder disorder by administering an unmethylated CpG sequence.

The claims recite an umethylated CpG sequence and the BCG vaccine comprises bacterial genomes and thus contains umethylated CpG sequences.

Peters *et al.* teach a method of modulating the immune response in a mammal that has a bladder disorder comprising determining if the subject had a bladder condition and administering umethylated CpG sequences by instillation into the bladder to treat a bladder disorder, interstitial cystitis, (paragraph spanning 2090- 2091) and BCG was first used to treat cancer (paragraph spanning 2093- 2094).

Peters *et al.* do not specifically state that bacterial infection is not detected at the time of administration of CpG, the subjects were screened to determine that the diagnosis was correct. Peters *et al.* do not specifically state that the immune response is modulated from a Th2 to a Th1 response but it is known in the art that CpG causes this type of response

Thus, Peters *et al.* anticipate the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 3, 9- 12, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters *et al.* (1997, from IDS), Tinsley-Brown *et al.* and Elkins *et al.*

The claims are drawn to a method of modulating the immune response in a mammal that has or is at risk of a bladder disorder by administering an unmethylated CpG sequence in the form of microparticles.

Peters *et al.* as discussed above teach that bacteria can be used to treat bladder conditions.

Peters *et al.* do not teach plasmids, or microparticles.

Elkins *et al.* teach that the CpG DNA element of bacterial DNA can confer protection (Table 2).

Tinsley-Brown *et al.* teach that polymer encapsidation to form microparticles is an effective method of delivering DNA to cells.

One of ordinary skill in the art at the time of invention would have known the risks (contamination and infection of the subject or others) of using live bacteria as taught by Peters *et al.* Knowing that Peters *et al.* uses bacteria, one of ordinary skill in the art at the time of invention would have been motivated to use the bacterial CpG DNA by itself because Elkins *et al.* teach that the CpG confers protection thus reducing the risk of using live bacteria. One of ordinary skill in the art would know that plasmids are convenient forms of working with DNA and that there are many ways to delivery the DNA such as taught in Tinsley-Brown *et al.*

The nucleic acid CpG oligonucleotides taught by Elkins *et al.* do not encode naturally occurring polypeptides.

Thus it would have been *prima facie* obvious to modify the bacteria used in the method of Peters *et al.* to use just DNA and administer by microparticles as taught by Tinsley-Brown *et al.* with the expectation of success in being able to treat bladder disorders more safely.

Claims 1, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters *et al.* (1997, from IDS), Elkins *et al.*, and Kohda *et al.*

The claims are drawn to a method of modulating the immune response in a mammal that has or is at risk of a bladder disorder by administering an unmethylated CpG sequence in the form of microparticles.

Peters *et al.* as discussed above teach that bacteria can be used to treat bladder conditions.

Elkins *et al.* teach that the CpG DNA element of bacterial DNA can confer protection (Table 2) and s discussed above.

Neither Peters *et al.* nor Elkins *et al.* teach alpha MSH.

Kohda *et al.* teach that alpha MSH is well known to be an anti-inflammatory peptide (abstract).

One of ordinary skill in the art at the time of invention would have known the method of Peters *et al.* is for treating bladder inflammation. One of ordinary skill in the art at the time of invention would have been motivated to treat with an additional agent

to obtain at least an additive effect. Kohda *et al.* do not teach delivery of nucleic acid but one of ordinary skill in the art at the time of invention would know that the sequence encoding the peptide could be administered in a structure that allows translation and production of the peptide.

Thus it would have been *prima facie* obvious to modify the method of Peters *et al.* to include a sequence that encodes alpha-MSH as taught by Kohda *et al.* with the expectation of success in being able to reduce more inflammation and thus reduce symptoms.

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Myron G. Hill
Patent Examiner
22 June 2004

JEFFREY STUCKER
PRIMARY EXAMINER